

SEP 14 2008

Application No.: 10/724,458

Docket No.: BEW-005

REMARKS

Applicants note with appreciation the indication of allowable subject matter in the instant application, namely, the subject matter recited in claims 4-6 and 16-18. Claims 1-24 were presented for examination, of which claims 1 and 13 are independent claims. Claims 1 and 13 have been rejected under 35 U.S.C. §102(e). Claims 1-3, 7-15 and 19-24 have been rejected under 35 U.S.C. §103(a). Claims 1 and 13 have been amended to incorporate the subject matter of claims 3 and 15, respectively. Accordingly, claims 3 and 15 have been canceled. The following comments address all stated grounds for rejection, and place the presently pending claims, as identified above, in condition for allowance.

Claim Amendments

Claims 1 and 13 have been amended to incorporate the subject matter from claims 3 and 15, respectively.

Claim Rejections under 35 U.S.C. § 102(e)

Claims 1 and 13 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,415,164 (Faupel). Applicants respectfully traverse these rejections.

Claims 1 and 13 are directed to a method and system for diagnosing the possibility of disease in a body part. The claimed invention provides an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part, and allows *an electrode assessment measurement* to be made with the electrode array, *as a bipolar measurement*, when the array is coupled to the body part. *The bipolar measurement utilizes one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair*. While the tetrapolar method is most accurate when measuring impedance, the bipolar measurement provides an advantage for determining adequacy of electrode-to-skin contact because a poor contact result can be isolated to one or both electrodes. The claimed invention further determines whether the plurality of electrodes are suitably coupled to the body part based on the electrode assessment measurement, which is implemented as a bipolar measurement. Determining whether the electrodes are suitably coupled is important because if one or more electrodes have lost contact with the skin,

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or if the contact with the skin is poor, errors can arise in the electrical measurements that then yield erroneous impedances.

Faupel, however, discusses an apparatus and method for measuring electrical characteristics of electrodes. For example, Faupel provides for measuring the DC offset of electrodes. Faupel provides an initialization period where the electrical characteristics of the electrodes are measured. To make the initialization period measurements *an electrode pair must be placed face to face with the gel from one electrode in contact with the gel of the other electrode*. Faupel also discusses providing a monitoring period to determine a settling time of a patient when the electrodes are applied. During this period, the DC activity of the skin surface is monitored in a continuous manner until the DC signals are within a predetermined tolerance. After it is determined that the average DC signals are within the predetermined tolerance DC biopotential measurements may begin.

Faupel fails to disclose an *electrode assessment measurement, as a bipolar measurement that utilizes one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair* when the plurality of electrodes are coupled to the body part. Rather, Faupel discusses an initialization period before biopotential the electrodes are attached to the test area, and a monitoring period for determining a settling down time. Neither of the periods discussed by Faupel disclose making a bipolar measurement that utilizes *one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair*.

For at least these reasons, Applicants respectfully contend that Faupel does not disclose all of the patentable features of claims 1 and 13, as amended. Applicants respectfully request the Examiner to reconsider and withdraw the rejections of Claims 1 and 13 under 35 U.S.C. § 102(e).

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Claims Rejected under 35 U.S.C. § 103(a)

Claims 1-3, 7-15 and 19-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,122,544 (Organ) in view of U.S. Patent No. 5,419,337 (Dempsey). Applicants respectfully traverse these rejections.

Neither Dempsey nor Organ teach or suggest a system that *determines whether the plurality of electrodes are suitably coupled to the body part based on the electrode assessment measurement, which is implemented as a bipolar measurement.*

Rather, Dempsey discusses a system using ECG strips whereby a user must use his own judgment to interpret data from a display to determine whether electrodes may have poor skin contact. See *Col. 5, Lines 12-29*. In contrast to Dempsey, the claimed invention determines whether the electrodes are suitably coupled to the body part.

Organ indicates that the electrode arrays "are made of an electrically conductive, self adhesive material so that when the array is positioned on the skin and pressed against it, the adhesive quality of the electrodes assure good skin fixation." See *Col. 4, Lines 4-8*. Organ, therefore does not teach or suggest a system that determines whether the electrode array is suitably coupled to the body part.

Further, neither Dempsey nor Organ teach or suggest *an electrode assessment measurement to be made with the electrode array when the array is coupled to the body part where the measurement is a bipolar measurement that utilizes one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair.*

Rather, Dempsey discusses a system using ECG strips. In contrast to Dempsey, the claimed invention makes an electrode assessment measurement, *as a bipolar measurement that utilizes one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair.* Dempsey, however, does not teach or suggest invoking impedance measurements between proximal current and voltage electrodes, as the ECG system discussed in Dempsey, by its nature, typical only has one

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type of electrode. As such, Dempsey fails to teach or suggest making an electrode assessment measurement, as a *bipolar measurement that utilizes one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair.*

Organ provides that “four electrodes must be used” to make measurements (e.g., a tetrapolar measurement). See Col. 4, Lines 46-49 [Emphasis Added]. In contrast to Organ, the claimed invention provides *bipolar* measurements that *utilizes one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair.* Organ, therefore, fails to teach or suggest making an electrode assessment measurement, as a *bipolar* measurement. While the tetrapolar method is most accurate when measuring impedance, a bipolar measurement provides an advantage for determining adequacy of electrode-to-skin contact because a poor contact result can be isolated to one or both electrodes.

In addition, Organ teaches away from the claimed invention Organ provides that “four electrodes must be used” and that the “adhesive quality of the electrodes assures good skin fixation.” The claimed invention, however, enables bipolar measurements and accounts for poor coupling of the electrodes to the skin by providing an electrode assessment measurements, as a *bipolar measurement that utilizes one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair to determine whether the electrodes are suitably coupled to the body part.*

Determining whether the electrodes are suitably coupled is important because if one or more electrodes have lost contact with the skin, or if the contact with the skin is poor, errors can arise in the electrical measurements that then yield erroneous impedances. The claimed invention provides a bipolar measurement for making the electrode assessment provides an advantage over the tetrapolar method when determining adequacy of electrode-to-skin contact because a poor contact result can be isolated to one or both electrodes. Further,

Applicants note that an attempt to combine Faupel with Dempsey and Organ would fail to teach or suggest all of the patentable features of the claimed invention, since neither Faupel,

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Dempsey nor Organ teach or suggest a making an electrode assessment measurement, as a bipolar measurement that utilizes *utilizes one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair.*

For at least these reasons, Applicants respectfully contend that neither Dempsey nor Organ teach or suggest, alone or in combination, all of the patentable features of claims 1 and 13, as amended. Claims 2-12 depend, directly or indirectly, on claim 1, and therefore incorporate all of the patentable features of claim 1. Claims 14-24 depend, directly or indirectly, on claim 13, and therefore incorporate all of the patentable features of claim 13. Applicants respectfully request the Examiner to reconsider and withdraw the rejections of Claims 1, 2, 7-14 and 19-24 under 35 U.S.C. § 103(a).

Claims 12 and 24 Rejected under 35 U.S.C. § 103(a)

Claims 12 and 24 depend on claims 1 and 13, respectively. Claims 12 and 24 have been rejected under 35 U.S.C. § 103 as being unpatentable over Organ in view of Dempsey. Applicants respectfully traverse.

Claims 12 and 24 add the additional limitation that provides *an indication of a status of the coupling* between the plurality of electrodes and the body part with a graphical user interface.

Neither Organ nor Dempsey teach or suggest *indicating a status of the coupling* between the plurality of electrodes. Rather, Organ simple provides “adhesive quality of the electrodes assure good skin affixation” and the display in Dempsey does not indicate a status of the coupling. In contrast to the claimed invention, a user in Dempsey must use his own judgment, based on actual measurements depicted on a display, to determine whether the electrodes have poor skin contact. The claimed invention requires indicating a status of the coupling.

For at least these reasons, Applicants respectfully contend that neither Dempsey nor Organ teach or suggest, alone or in combination, all of the patentable features of claim 12. Applicants respectfully request the Examiner to reconsider and withdraw the rejections of claims 12 under 35 U.S.C. § 103(a).

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Conclusion

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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